International Standard

ISO 11139

First edition
2018-08

AMENDMENT 1
2024-01

Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards

AMENDMENT 1: Amended and additional terms and definitions

Stérilisation des produits de santé — Vocabulaire des termes utilisés dans les normes de procédés de stérilisation et les équipements connexes

AMENDEMENT 1: Termes et définitions modifiés et supplémentaires

Reference number
ISO 11139:2018/Amd.1:2024(en)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers and associated equipment for processing of medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards

AMENDMENT 1: Amended and additional terms and definitions

3.111 exposure phase

Replace the term and the text of the definition with the following:

3.111
exposure stage
cycle stage between the introduction of the sterilizing agent or disinfecting agent into the chamber and when its microbicidal effect has become negligible

Note 1 to entry: The exposure stage comprises that part of the process for which microbial lethality is claimed.

3.113.2 F_{BIO} value

Replace the text of the definition with the following:

3.113.2
F_{BIO} value
expression of the resistance of a biological indicator calculated as the product of the logarithm to base 10 of the initial population of microorganisms and the *D* value

Add the following new entry 3.113.4 $F_{BIOLOGICAL}$ value:

3.113.4
$F_{BIOLOGICAL}$ value
expression of the delivered lethality of a process, measured in terms of actual kill of microorganisms on or in a biological indicator (BI) challenge system

Note 1 to entry: $F_{BIOLOGICAL}$ can be calculated by multiplying the D_{121} value by the difference between the log to the base ten of the starting population and the log to the base ten of the enumerated population after processing.

3.133 holding time

Replace the text of the definition with the following:

3.133
holding time
period during which process or cycle parameters are maintained within their specified tolerances for defined cycle stages

Add the following new entry 3.133.1 holding time:

3.133.1
holding time
<moist heat sterilization> period for which the temperatures at the reference measurement point, and at all points within the load, are continuously within the sterilization temperature band

3.151 labelling

Replace the text of the definition with the following:

3.151
labelling
label, instructions for use and any other information related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents

[SOURCE: ISO 13485:2016, 3.8]

3.166 medical device

Added "in or on the human body" in the paragraph after the list, as follows:

3.166
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, or software material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

— diagnosis, prevention, monitoring, treatment, or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of, or compensation for an injury;

— investigation, replacement, modification, or support of the anatomy, or of a physiological process;

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information by means of in vitro examination of specimens derived from the human body;

and which does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions, but not in others include:

— items specifically intended for cleaning or sterilization of medical devices;

— pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization;

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for in vitro fertilization or assisted reproduction technologies.

3.214 processing